UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,862	06/13/2006	Per Holm	134391.00114	2548

64574 7590 10/22/2010

BLANK ROME LLP
ONE LOGAN SQUARE
PHILADELPHIA, PA 19103

EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
10/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/569,862	HOLM ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 07 September 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-10,20-25,27-29,31-37,40-44,51 and 52*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
    See Continuation Sheet.

12. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). 9/7/10, 12/9/09

13. ☒ Other: See Continuation Sheet.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618

Continuation of 5. Applicant's reply has overcome the following rejection(s): obviousness type double patenting of claims 1-44 and 51 over claims 59,66,72-74,83-85 and 90 of copending 10/574,125 and claims 1,3-11,13-29,31-34,36,37,40,44 and 53-56 of copening 10/569,863. Copending 11/885,992 has been abandoned so the rejection has been withdrawn.

Continuation of 11. does NOT place the application in condition for allowance because: The prior art continues to obviate the instant claims by disclosing a tablet comprising tacrolimus, polyethylene glycol and Poloxamer. The '942 patent discloses a tablet formulation comprising tacrolimus and polyethylene glycol and is silent to Poloxamer. The '939 patent discloses capsule or tablet formulations comprising water insoluble drugs (tacrolimus is water insoluble) in combination with polyethylene glycol and poloxamers. The combination of carrier compounds improves the solubility of the poorly water soluble drug and would have been an obvious combination in order to improve the solubility and bioavailability of the '942 formulation. Applicant argues that the art cannot be combined since the '942 patent discloses a fast release formulation and the '939 patent discloses a sustained release formulation. However these fast and sustained release labels are relative to the individual dissolution test given. The formulations are similar in that they both provide water insoluble drug in combination with polyethylene glycol of the same molecular weight range in tablet form. The combination would have been obvious with the '939 patent providing an improvement to the formulation. Application also argues that the artisan of ordinary skill would not have been able to form tablets using the '942 formulation. Applicant argues that the components would not be ideal for compression tableting, i.e. punch-die systems. However it is the position of the Examiner that the artisan of ordinary skill would recognize this limitation and simply use another tableting method such as molding or extrusion. The prior art nor the claim specifically recite tableting method steps beyond forming the tablet. As such any method that results in a tablet comprising tacrolimus polyethylene glycol and Poloxamer would meet the limitations of the claims. Various means of tableting are well-known in the art. For these reasons the claims remain obviated .

Continuation of 13. Other:

In view of the papers filed September 7, 2010, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by deletion of the following previously unnamed inventors of this application: Tomas Norling
The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected